K101956

SEP 29 2010

SPECIAL 510k SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Submitter and Contact Person:	AMSINO International, Inc 855 Towne Center Drive, Pomona, CA 91767 Jesus T. Farinas Manager, Quality Assurance and Regulatory Affairs
Establishment Number:	**2085175**
Name of the Device:	
Classification Name:	Set, Administration, Intravascular
Proprietary Name:	*AMSINO® I.V. ADMINISTRATION SET AND EXTENSION SET*
510k number:	
Regulation Number:	**880.5440**
Class:	**II**
Classification Product Code:	**FPA**

Predicate Devices:
AMSINO® I.V ADMINISTRATION SET (k973107)and (k093773)

Intended use of the Device:

The *AMSINO® I.V. ADMINISTRATION EXTENSION SET* is a device intended to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein.

Device Description:

The *AMSINO® I.V. ADMINISTRATION EXTENSION SET* is a single use, latex-free, Non-DEHP, gravity feed, sterile device sterilized with Ethylene Oxide Gas. It is used to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein. The EXTENSION SET will provide a tubing extension to increase the length of an I.V. set or a syringe. The Extension Set consists of various parts such as: drip chamber, luer adapter/connectors, clamp, tubing, flow controller, Y-site, latex-free injection port, needleless injection port, stopcock, flashbulb, filter and manifold.

This submission is an extension of the original approval (per k973107) and (k093773).

Technological Characteristics Summary:

AMSINO® I.V. ADMINISTRATION EXTENSION SET are constructed of high grade extruded DEHP-free PVC. Component material list is herewith attached (see device drawings). The intended use, the basic design, function and the materials used to construct the IV Administration Set and the Extension Sets are identical to the predicate device and other devices currently legally marketed and are substantially equivalent. This premarket notification is an update of the performance and biocompatibility data of the currently approved predicate device – the Amsino I.V. Administration Set (k971037) and (k093773)

Performance Data

The *AMSINO® I.V. ADMINISTRATION SETS* ***k973107), and (K093773)*** *have been shown t0* meet the Bench performance testing requirement according to ISO 8536-4 when appropriate and/or AMSINO's testing and acceptance criteria:

Closure Piercing Device (Spike) Features
Air Inlet Device Characteristics
Connector Performance criteria: i.e. to prevent leakage
Drip Chamber and Drip Tube Performance
Flow Regulator Performance
Flow characteristics
Tensile Strength of Connectors
Self-sealing injection site challenge test
The number of injection port access to failure for needleless port with valves, diaphragms or membrane.

Additional testing for Leakage (Vacuum Tightness and Air Tightness), and Flow Rate of Infusion Fluid, of extension sets attached to a master IV Administration Set was performed to demonstrate the stability of the extension set.

Biocompatibility and Hemocompatibility:

Biocompatibility assessment of the *AMSINO® I.V. ADMINISTRATION SET* has been conducted (see k093773) based on the guidelines established by various governmental and standard setting organizations such as ISO 10993-1- Biological Evaluation of Medical Devices. Based upon the results of this prolonged duration, indirect blood path containing device assessment; (Cytoxicity, Sensitization, Irritation, Systemic Cytoxicity and Hemocompatibility testing) the materials used to fabricate the *AMSINO® I.V. ADMINISTRATION SET AND EXTENSION SET,* has been shown to be biocompatible, hemocompatible, and appropriate for its intended use.

Sterility:

AMSINO® I.V. ADMINISTRATION EXTENSION SET is sterilized by Ethylene Oxide as validated per ISO 11135-1:2007-Sterilization of Healthcare products – Ethylene Oxide - Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices. (See k093773)

Pyrogenicity: *AMSINO® I.V. ADMINISTRATION EXTENSION SET* is tested for pyrogenicity (See k093773)).

Microbial Ingress Testing: Amsino's testing of potential microbial ingress demonstrates a 4-log reduction of micro-organisms against gram negative and gram positive organisms using the proper aseptic technique. (See k093773)

The *AMSINO® I.V. ADMINISTRATION EXTENSION SET* is substantially equivalent to the predicate devices in technology, materials used and intended use as the *AMSINO® I.V. ADMINISTRATION SET (k973107), and (K08Medegen Intravascular IV Set and Extension (k093773).*

Submitted by:

Jesus Farinas
Senior Manager, QA/RA

Date 07 JULY 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Jesus Farinas
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SEP 29 2010

Re: K101958
Trade/Device Name: AMSINO® I.V. ADMINISTRATION SET AND EXTENSION SET
Regulation Number: 21 CFR 880.5440
Regulation Name: Neonatal Incubator
Regulatory Class: II
Product Code: FPA
Dated: September 9, 2010
Received: September 10, 2010

Dear Mr. Farinas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

SEP 2 9 2010

510(k) Number (if known): K101958

Device Name: *AMSINO® I.V. ADMINISTRATION SET AND EXTENSION SET*

Indications For Use:

The *AMSINO® I.V. ADMINISTRATION EXTENSION SET* is a device intended to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein.

Prescription Use__X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 9/27/10
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101958